Complete Summary

GUIDELINE TITLE

The management of early pregnancy loss.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). The management of early pregnancy loss. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 18 p. (Green-top guideline; no. 25). [75 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Early pregnancy loss

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To review recent information related to the diagnosis and clinical management of women with early pregnancy loss, defined as a loss within the first 12 completed weeks of pregnancy

TARGET POPULATION

Women with pregnancy loss within the first 12 completed weeks of pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis and Investigation

1. Transvaginal ultrasound
2. Serial serum human chorionic gonadotrophin (hCG) level
3. Serum progesterone level

Management/Treatment

1. Use of appropriate medical terminology for pregnancy loss
2. Service provision
    - Provision of a dedicated outpatient early pregnancy assessment unit (EPAU)
    - Development of diagnostic and therapeutic algorithms of care for the management of suspected ectopic pregnancy, intrauterine pregnancy of uncertain viability and for pregnancy of unknown location by EPAUs.
3. Anti-D immunoglobulin (for nonsensitized rhesus [Rh] negative women)
4. Screening for infection (e.g., *Chlamydia trachomatis*)
5. Uterine evacuation for miscarriage
    - Surgical uterine evacuation(suction curettage, local anesthesia/sedation)
    - Medical uterine evacuation
6. Expectant management of first-trimester miscarriage
7. Histologic examination of tissue passed at miscarriage
8. Support, counseling, and follow up

MAJOR OUTCOMES CONSIDERED

- Rates of complete miscarriage, incomplete miscarriage, missed miscarriage, miscarriage with infection, recurrent miscarriage
- Patient satisfaction with elements of the early pregnancy assessment unit (EPAU) service
- Complications of the various interventions (including failure rates)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A search of Medline, Embase and Cochrane, 1999–2006, as well as Royal College of Obstetricians and Gynaecologists (RCOG) publications, was undertaken to include relevant systematic reviews, meta-analyses, randomised controlled trials, and other clinical trials. The search words used were "miscarriage," "spontaneous abortion," "uterine evacuation," "mifepristone," "prostaglandin (misprostol)," and "progesterone."

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analyses of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based. The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group of the National Health Service Executive.

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)

Grade B - Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

COST ANALYSIS

Published cost analyses were reviewed that evaluated medical versus surgical evacuation of miscarriage. Medical evacuation has potential economic benefits for the National Health Service (NHS), with an average cost saving of 50 pounds sterling/case.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following discussion in the Guidelines and Audit Committee, each green-top guideline is formally peer reviewed. At the same time the draft guideline is published on the Royal College of Obstetricians and Gynaecologists Web site for further peer review discussion before final publication.

The names of author(s) and nominated peer reviewers are included in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Levels of evidence (**Ia-IV**) and grading of recommendations (**A-C**) are defined at the end of the "Major Recommendations" field.

Appropriate Terminology

C - The recommended medical term for pregnancy loss under 24 weeks is "miscarriage." The word "miscarriage" should be used in clinical practice and its use should be strongly encouraged in textbooks and scientific journals.

When talking to women, the inadvertent use of inappropriate terms such as "pregnancy **failure**" or "**incompetent** cervix" can contribute to negative self-perceptions and worsen any sense of failure, shame, guilt, and insecurity. (Evidence level IV).

The terms in the table below are recommended.

Previous Term	Recommended Term
Spontaneous abortion	Miscarriage
Threatened abortion	Threatened miscarriage
Inevitable abortion	Inevitable miscarriage
Incomplete abortion	Incomplete miscarriage
Complete abortion	Complete miscarriage
Missed abortion/anembryonic pregnancy/blighted ovum (these reflect different stages in the same process)	Missed miscarriage Early fetal demise Delayed miscarriage Silent miscarriage
Septic abortion	Miscarriage with infection (sepsis)
Recurrent abortion	Recurrent miscarriage

The European Society for Human Reproduction Special Interest Group for Early Pregnancy has published revised nomenclature for use in early pregnancy loss in order to improve clarity and consistency. The following are some of the pertinent recommendations (Evidence level IV):

Term	Definition
Biochemical pregnancy loss	Pregnancy not located on scan
Empty sac	Sac with absent or minimal structures
Fetal loss	Previous CRL measurement with subsequent loss of fetal heart activity (FHA)
Early pregnancy loss	Confirmed empty sac or sac with fetus but no FHA <12 weeks
Delayed miscarriage	As "early pregnancy loss"
Late pregnancy loss	Loss of FHA >12 weeks
Pregnancy of unknown location	No identifiable pregnancy on scan with positive hCG

CRL = crown-rump length

hCG = human chorionic gonadotrophin

Service Provision

What Is the Ideal Setting for Assessment of Women with a Potential Diagnosis of Early Pregnancy Loss?

C - All units should provide a dedicated outpatient early pregnancy assessment service. There are clinical and economic benefits associated with this type of service.

What Are the Requirements for Running an Effective Early Pregnancy Assessment Unit Service?

C - The early pregnancy assessment units (EPAU) service should be comprehensive and ideally sited in a dedicated area with appropriate staffing. There should be direct access for general practitioners (GPs) and selected patient groups.

To be effective, an EPAU requires an efficient appointments system, an appropriate setting, ultrasound equipment (including transvaginal probes), and easy access to laboratory facilities for rhesus antibody testing and selective serum human chorionic gonadotrophin (hCG) and progesterone estimation. The service should be available on a daily basis during the normal working week, although many units offer an additional limited service at weekends. Standardised information leaflets, referral and discharge letters should be available and regularly reviewed. Certain patient groups, such as women who have had a previous ectopic pregnancy and those with repeated or recurrent miscarriage, can be offered future access to the service by direct self-referral via the appointments system. (Evidence level IV)

Diagnosis and Investigation

What Is the Role of Transvaginal Ultrasound in the EPAU Setting?

C - EPAUs should have access to transvaginal ultrasound (TVS) with staff appropriately trained in its use.

How Should Cases of Suspected Early Pregnancy Loss Be Managed in the EPAU?

C - EPAUs should use and develop diagnostic and therapeutic algorithms of care. In particular, these should be available for the management of suspected ectopic pregnancy, intrauterine pregnancy of uncertain viability, and for pregnancy of unknown location.

"Indeterminate" is a term used in clinical practice that has led to confusion. Some practitioners have used the term to mean "pregnancy of indeterminate site" while others mean "pregnancy of indeterminate viability." This present revision recommends that "indeterminate" should no longer be used but should be replaced with the two separate terms below. Both terms should only be used after assessment by TVS. (Evidence level IV)

- Pregnancy of unknown location: No signs of either intra- or extrauterine pregnancy or retained products of conception in a woman with a positive pregnancy test.
- Pregnancy of "uncertain viability": Intrauterine sac (<20 mm mean diameter) with) no obvious yolk sac or fetus
  or
  Fetal echo <6 mm crown–rump length with no obvious fetal heart activity. In order to confirm or refute viability, a repeat scan at a minimal interval of 1 week is necessary.

A basic diagnostic algorithm has been appended in the original guideline document guideline (see Appendix 1 in the original guideline document) that includes the terminology described above, with the aim of encouraging a consistent approach across EPAUs. TVS is only one part of the diagnostic process in the assessment of potential early pregnancy loss. Women should be managed within a unit-specific guideline that includes use of serum hCG assay. (Evidence level IV)

What Is the Role of Serial hCG Assessment in Predicting Pregnancy Outcome?

B - Serial serum hCG assay is particularly useful in the diagnosis of asymptomatic ectopic pregnancy.

Early ectopic pregnancy can be difficult to diagnose and the RCOG Study Group concluded that access to serial serum hCG estimation is essential, with results available within 24 hours. Staff must be familiar with what is an acceptable normal rise in 48 hours. Although a doubling of hCG titre is often expected, this can vary depending on gestation.

Serum hCG levels need caution in interpretation. In cases of twin pregnancy or heterotopic pregnancy, a suboptimal rise may be misleading.

Women with miscarriage or ectopic pregnancy who are managed expectantly may also require serial serum hCG monitoring.

Does Serum Progesterone Assay Have a Role in Predicting Pregnancy Outcome?

B - Serum progesterone can be a useful adjunct when ultrasound suggests pregnancy of unknown location. TVS, serial serum hCG levels, and progesterone may all be required in order to establish a definite diagnosis.

Should All Women with Early Pregnancy Loss Receive Anti-D Immunoglobulin?

B - Non-sensitised rhesus (Rh) negative women should receive anti-D immunoglobulin in the following situations: ectopic pregnancy, all miscarriages over 12 weeks of gestation (including threatened), and all miscarriages where the uterus is evacuated (whether medically or surgically).

C - Anti-D immunoglobulin should only be given for threatened miscarriage under 12 weeks gestation when bleeding is heavy or associated with pain. It is not required for cases of complete miscarriage under 12 weeks of gestation when there has been no formal intervention to evacuate the uterus.

Treatment

Which Women Should Be Screened for Genital Tract Infection?

C - Screening for infection, including *Chlamydia trachomatis*, should be considered in women undergoing surgical uterine evacuation.

Should Prophylactic Antibiotics Be Given Prior to Surgical Evacuation?

A - There is insufficient evidence to recommend routine antibiotic prophylaxis prior to surgical uterine evacuation.

When Should Surgical Uterine Evacuation Be Used?

C - Surgical uterine evacuation should be offered to women who prefer that option. Clinical indications for offering surgical evacuation include persistent excessive bleeding, haemodynamic instability, evidence of infected retained tissue, and suspected gestational trophoblastic disease.

How Should Surgical Uterine Evacuation Be Performed?

A - Surgical uterine evacuation for miscarriage should be performed using suction curettage.

C - Consideration should be given to offering surgical evacuation techniques under local anaesthesia or sedation for those women who prefer that approach.

What Are the Alternatives to Surgical Uterine Evacuation for Miscarriage?

A - Medical methods are an effective alternative in the management of confirmed first-trimester miscarriage.

The published literature on a wide range of therapeutic regimens is summarised in Appendix 2 in the original guideline document.

A - Expectant management is another effective method to use in selected cases of confirmed first-trimester miscarriage.

Expectant management is an effective and acceptable method to offer women who miscarry. Patient counselling is particularly important for those women with an intact sac who wish to adopt an expectant approach. They should be aware that complete resolution may take several weeks and that overall efficacy rates are lower. They may wish to consider a medical approach or to commence expectant management with the option of surgical evacuation at a later date if required. Expectant management for incomplete miscarriage is highly effective. (Evidence level Ib)

Expectant management is often followed by minimal bleeding, as any retained tissue will usually undergo resorption. Occasionally, the passage of tissue may be associated with heavy bleeding. In cases of missed miscarriage, managed using antiprogesterone/prostaglandin combinations, one-third of women will bleed or miscarry in the priming phase after antiprogesterone. It is important that all women undergoing medical or conservative management have direct telephone access to ward staff for advice and support. Emergency beds must be available should they require admission. (Evidence level IV)

What Are the Advantages of Arranging Histological Examination of Tissue Passed at the Time of Miscarriage?

C - Tissue obtained at the time of miscarriage should be examined histologically to confirm pregnancy and to exclude ectopic pregnancy or unsuspected gestational trophoblastic disease.

Women who miscarry at home and are admitted to hospital should be advised to take with them any tissue passed so that histological examination can be arranged. Alternatively, the attending practitioner should arrange for the appropriate examination.

Psychological Aspects of Early Pregnancy Loss

Is There Potential Benefit from Support and Follow-up after Pregnancy Loss?

A - All professionals should be aware of the psychological sequelae associated with pregnancy loss and should provide support, follow-up, and access to formal

counselling when necessary. Appropriate support can result in significant positive psychological gain.

Should Care Providers Encourage Patient Choice in Deciding Which Intervention to Use to Achieve Uterine Evacuation?

A - In terms of therapeutic intervention, patient choice should be encouraged, as it is associated with positive quality-of-life outcomes.

Definitions:

Grading of Recommendations

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Levels of Evidence

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CLINICAL ALGORITHM(S)

The "Basic Diagnosis Algorithm for Early Pregnancy Loss" is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of women with early pregnancy loss

POTENTIAL HARMS

- Bleeding may continue for up to 3 weeks after medical uterine evacuation.
- Reported serious complications of surgery include perforation, cervical tears, intra-abdominal trauma, intrauterine adhesions, and hemorrhage
- With expectant management, the passage of tissue may be associated with heavy bleeding.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are "systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions." Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: Guidance for the Development of RCOG Green-top Guidelines (See the "Availability of Companion Documents" field in this summary.)
- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). The management of early pregnancy loss. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 18 p. (Green-top guideline; no. 25). [75 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Oct

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

Royal College of Obstetricians and Gynaecologists

GUIDELINE COMMITTEE

Guidelines and Audit Committee of the Royal College of Obstetricians and Gynaecologists

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Guideline authors are required to complete a "declaration of interests" form.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the RCOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Development of RCOG green-top guidelines: policies and processes. Clinical Governance Advice No 1a. 2006 Nov. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Development of RCOG green-top guidelines: producing a scope. Clinical Governance Advice No 1b. 2006 Nov. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Development of RCOG green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. 2006 Nov. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Searching for evidence. Clinical Governance Advice No 3. 2001 Oct. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Additionally, auditable standards can be found in section 9 of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

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